# PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

To:

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NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Rule 71.1)

Date of mailing *(day/month/year)* 10.02.2005

Applicant's or agent's file reference
JNR/PG4977

**IMPORTANT NOTIFICATION**

| International application No. | International filing date *(day/month/year)* | Priority date *(day/month/year)* |
|---|---|---|
| PCT/EP 03/12159 | 30.10.2003 | 02.11.2002 |

Applicant
GLAXO GROUP LIMITED et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international preliminary examining authority:

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# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

| Applicant's or agent's file reference JNR/PG4977 | **FOR FURTHER ACTION** | See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) |
|---|---|---|
| International application No. PCT/EP 03/12159 | International filing date *(day/month/year)* 30.10.2003 | Priority date *(day/month/year)* 02.11.2002 |
| International Patent Classification (IPC) or both national classification and IPC B65D75/34 | | |
| Applicant GLAXO GROUP LIMITED et al. | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 9 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☒ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

| Date of submission of the demand | Date of completion of this report |
|---|---|
| 07.05.2004 | 10.02.2005 |
| Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 | Authorized Officer Bevilacqua, V Telephone No. +49 89 2399-7983 |

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP 03/12159

## I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

**Description, Pages**

1-29 as originally filed

**Claims, Numbers**

1-29 as originally filed

**Drawings, Sheets**

1/2-2/2 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   *(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**IV. Lack of unity of invention**

1. In response to the invitation to restrict or pay additional fees, the applicant has:

   ☐ restricted the claims.

   ☐ paid additional fees.

   ☐ paid additional fees under protest.

   ☒ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

   ☐ complied with.

   ☐ not complied with for the following reasons:

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1-7,15-27 .

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

| | | | |
|---|---|---|---|
| Novelty (N) | Yes: | Claims | 15-27 |
| | No: | Claims | 1-7 |
| Inventive step (IS) | Yes: | Claims | |
| | No: | Claims | 15-27 |
| Industrial applicability (IA) | Yes: | Claims | 1-7,15-27 |
| | No: | Claims | |

2. Citations and explanations

   **see separate sheet**

**Re Item IV**
**Lack of unity of invention**

1. The international preliminary examining authority is of the opinion that the claims 1-27 of the present application do not comply with the requirements of unity of invention as set forth in the PCT regulations (Article 34(3), Rule 68(1) PCT).

2. The separate inventions are:
   a) A blister form medicament pack comprising a base sheet in which blisters are formed to define pockets therein and a lid sheet which is sealable to the base sheet and peelable from the base sheet wherein the base sheet or the lid sheet have a laminate structure comprising a first layer of aluminium foil and a second layer made of one of many possible polymeric materials having optimized thickness in order to achieve low water vapour permeability according to any of claims 1-7 and 15-27.

   b) A blister form medicament pack comprising a base sheet in which blisters are formed to define pockets therein and a lid sheet which is sealable to the base sheet and peelable from the base sheet wherein the base sheet or the lid sheet have a laminate structure comprising a first layer of aluminium foil and a second layer made of polymeric material whereby thelid sheet has a particular layer composition according to any of claims 8-14.

This application relates to the general problem of enhancing the storage stability of medicament packed in blister type packages.

This problem is solved by the combination of features of independent claim 1, but these features are already known.
Document US 6,337,113 (D1) discloses:
a blister pack comprising a base sheet in which blisters are formed and a lid sheet which is sealeble to the base sheet except in the region of the blisters (see column 1 lines 14-30) and mechanically peelable from the base sheet to enhable release of said medicament (see column 8 lines 19-20), wherein said base sheet or said lid sheet have a laminate structure comprising first layer of aluminium foil and a second layer of polymeric material of thickness from 10 to 60 micron (see column 1 lines 54-60), said

polymeric material having a water vapour permeability of less than 0,6 g/(100 square inches) (24 hours) mil at 25 °C (and for example HDPE, disclosed at column 3 line 6 has this property).

The features common to independent claims 1, 28 and 29 are the features of independent claim 1 and being these already known in combination cannot be considered as special technical features (see Rule 13.2 PCT), no common inventive concept is therefore present between the independent claims .

Document D1 also deprives claims 2-7 , 16,17,18 and 19 of novelty, see for example:

-column 8 lines 39-41 where the medicament pack takes the form of an elongated peelable blister strip having multiple distinct blister portions provided along its length (claim 5)
-the "preferred example" at column 5 with a thickness of a second layer of oriented PP (claim 3) comprised between 20 and 30 micron (claim 7)

In addition to that, even if document D1 doesn't disclose in detail the possible moisture sensitive pharmaceutical products which could be contained it the disclosed blister pack no inventive step would be needed to use this known container for the packaging of all the pharmaceutical products of claims 23 to 27 as the advantage achieved (moisture protection) can be contemplated in advance.

The subject matter of claims 23 to 27 lacks therefore inventive step (Article 13(2) PCT)

The claims containing special technical features, defining a contribution which each of the claimed inventions considered as a whole makes over the prior art represented by D1 are as follows:

The subject matter of claims 15 and 20-22 (first invention) solves the problem of optimizing the moisture protection offered by the base sheet.

The features solving this problem are carefully selected materials and particular layer thicknesses of the base sheet.

The subject matter of claims 8-14 (second invention) solves the problems of optimizing the balance of properties of the lid sheet.

The features solving this problem are carefully selected materials and particular layer thicknesses of the lid sheet.

Thus the special technical features (analysed above) of each invention are clearly not the same. Furthermore, they are not "corresponding", since, as can be seen from the above analysis, they have neither the same nor corresponding effects, nor are they relating to the same objective.

Consequently, neither the objective problem underlying the subjects of the two inventions, nor their solutions defined by the (special) technical features allow for a relationship to be established between the said two inventions which involves a single general inventive concept.

In conclusion, therefore, the two groups of claims are not linked by a common or corresponding special technical features and define different inventions not linked by a single general inventive concept.

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. State of the art

Reference is made to the following documents:

D1: US-B-6 337 1131 (PASBRIG ERWIN ET AL) 8 January 2002 (2002-01-08)

D2: US-B-6 270 8691 (BREITLER HANS PETER ET AL) 7 August 2001 (2001-08-07) 11-28)

2. Novelty

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT, in fact Document D1 discloses:

a blister pack comprising a base sheet in which blisters are formed and a lid sheet which is sealeble to the base sheet except in the region of the blisters (see column 1 lines 14-30) and mechanically peelable from the base sheet to enhable release of said medicament (see column 8 lines 19-20), wherein said base sheet or said lid sheet have a laminate structure comprising first layer of aluminium foil and a second layer of polymeric material of thickness from 10 to 60 micron (see column 1 lines 54-60), said polymeric material having a water vapour permeability of less than 0,6 g/(100 square inches) (24 hours) mil at 25 °C (and for example HDPE, disclosed at column 3 line 6 has this property).

Document D1 also deprives claims 2-7 of novelty, see for example:
-column 8 lines 39-41 where the medicament pack takes the form of an elongated peelable blister strip having multiple distinct blister portions provided along its length (claim 5)

-the "preferred example" at column 5 with a thickness of a second layer of oriented PP (claim 3) comprised between 20 and 30 micron (claim 7)

3. Inventive step

3.1 Dependent claims 23-27 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step, the reasons being as follows:

- a blister medicament pack has already been employed to contain inhalable medicament in dry powder form, see document D2 column 1 line 39 and column 6 line 31 (claim 23)

-the subject-matter of claims 24-27 consists in the indication that the medicament to be contained is to be selected from a range of well known medicaments; such a selection can only be regarded as inventive, if the obtained combination of features presents un-

expected effects or properties, which is not the case, as the advantage achieved (moisture protection) can be contemplated in advance.

The subject matter of claims 23 to 27 lacks therefore inventive step (Article 13(2) PCT).

3.2 D1, which is considered to represent the most relevant state of the art, discloses a blister form medicament pack from which the subject-matter of claim 15 differs in that the base sheet additionally comprises an oriented polyamide layer, and in that this layer is adhesively bonded to the aluminium foil, which is adhesively bonded to the polymeric layer.

The problem to be solved by the present invention may therefore be regarded as how to further reduce the moisture permeability of the base sheet.

The solution proposed in claim 15 of the present application cannot be considered as involving an inventive step (Article 33(3) PCT) because document D2 discloses ( see figure 1, from column 1 line 35 to column 2 line 25 and column 4 lines 55-65):

-a base sheet comprising in succession: an oriented polyamide layer, adhesively bonded to an aluminium foil, adhesively bonded to a polymeric layer.

The skilled person would therefore regard it as a normal option to include an OPA layer on the free side of the aluminium foil in order to solve the problem posed.

3.3 Dependent claims 16 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step, the reasons being as follows:

- a OPP layer (claim 16) having 23 to 30 micron thickness is disclosed in D2 (see column 2 lines 11-13)

- a materials indicated in claims 17-22 are all already used in D1 or in D2 for the same purpose (for example a cast PP film is disclosed both in D1, see column 3 line 13 and in D2, see column 2 line 21-22); the layer thicknesses indicated in claim 17-20 and 22 are

not directly disclosed in D1 or D2, but can only be regarded as inventive, if they could generates unexpected effects or properties of the laminate, however, no such effects or properties are indicated in the application, hence, no inventive step is present in the subject-matter of claims 17-22 .